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IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CASE NO. 2:20-cv-00337-JRG
	)	
DAIICHI SANKYO CO., LTD.,	)	
	)	[redacted]
Defendant, and	)	
	)	
ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LTD.,	)	
	)	
Intervenor-Defendants.	)	

DEFENDANTS' SUR-REPLY IN SUPPORT OF ITS OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE PORTIONS OF THE EXPERT REPORTS OF JOHN M. LAMBERT, PH.D.

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A. Dr. Lambert's Non-infringement Analysis Is Based on the POSA's Understanding of the Claim as a Whole

Dr. Lambert's Responsive Report appropriately presents a full non-infringement analysis using the Court's claim constructions as applicable based on the understanding of the POSA in view of the claims as a whole.[1] Dr. Lambert's analysis explicitly acknowledges and applies the Court's constructions, and thus does not seek to re-hash any prior claim construction arguments.

Further, Seagen misstates the Court's *Markman* Order. Rather than adopting the construction offered by either Party, the Court relied on the lexicographical definition for "intracellularly cleaved" "with the rest of the phrase having its plain and ordinary meaning."[2] Dr. Lambert's analysis is fully consistent with this approach, and should be heard by the jury.

Seagen acknowledges that the Asserted Claims are directed to a whole ADC, and must be analyzed as a whole.[3] This requires the POSA to use the Court's constructions for the terms construed, the plain and ordinary meaning where the Court directs it, and the plain and ordinary meaning for the portions of the claim that the Court did not construe.[4] Seagen agrees that the Court's reference to plain and ordinary meaning was directed to "the rest of the phrase," given the Court only construed "intracellularly cleaved."[5] The entire phrase includes other concepts including that it is "the drug moiety" that is intracellularly cleaved and that the cleavage must be "in a patient." The POSA therefore must, at a minimum, consider how "the drug moiety" of the ADC must behave "in a patient." Dr. Lambert's conclusion that the drug moiety alone must be cleaved from the linker is, therefore, appropriately based on the plain meaning of the phrase as a

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[1] *See* Dkt. No. 265, Ex. 2, Lambert Responsive Report Section VII.
[2] *Markman* Order, Dkt. 155 at 40-42. While Plaintiff was trying to read out the latter aspects of the term at issue, the Court specifically noted that the rest of the phrase has its plain and ordinary meaning. *See Markman* Hearing Transcript (Aug. 27, 2021) at 96-99.
[3] Dkt. No. 275 at Section E.
[4] Dkt. No. 265 at 2-3.
[5] Dkt. No. 275 at 1.

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whole, as well as the context of the rest of the Asserted Claims and the '039 patent.

B. References to Dr. Morita's Testimony are Relevant to Considerations of Weight and Credibility of Evidence

Seagen's focus on whether Dr. Morita may be affirmatively used as a fact witness is irrelevant here. Dr. Lambert does not rely on Dr. Morita for new factual information to form his opinions.[6] Dr. Lambert explicitly states that he conducted his own independent analysis and formed his own conclusions.[7] Seagen, in fact, quotes Dr. Lambert's report where he states "I conclude the same ***based on my own review*** of the documents" showing Seagen recognizes this fact.[8] Rather, Seagen appears to dispute whether Dr. Lambert's analysis is sufficiently reasoned or credible. It is. Regardless, that is exactly the type of question the jury should be able to consider. Further, as explained in Defendants' Opposition, Seagen is not prejudiced by Dr. Lambert's reference to Dr. Morita's statements as Seagen sought to have Dr. Morita testify, and its own expert similarly cites to Dr. Morita's testimony in her own reports.[9]

C. The Jury Should Consider Dr. Lambert's Full Enablement and Written Description Analyses

Seagen's statement that Dr. Lambert "offers no opinion on enablement as of 2019"[10] misses the point. Seagen misinterprets Defendants' reliance on post-2004 art. That art demonstrates that Seagen's claimed invention was not enabled as of dates long after 2004, and so could not have been enabled as of 2004. Defendants' post-2004 citations illuminate the state of the art as of 2004, just as *Amgen* and other controlling precedent contemplate.[11] The Federal

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[6] Dkt. No. 265 at 5-6.
[7] Dkt. No. 265, Ex. 2, Lambert Responsive Report ¶¶ 143, 145.
[8] Dkt. No. 275 at 1-2.
[9] *But see GREE, Inc. v. Supercell Oy*, No. 2:19-cv-70-JRG-RSP, Dkt. 354, slip op. at 5 (E.D. Tex. July 26, 2020).
[10] Dkt. No. 275 at 2.
[11] *Amgen Inc. v. Sanofi,* 872 F.3d 1367, 1375 (Fed. Cir. 2017). Moreover, unlike in *Amgen*, the

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Circuit has held that excluding such evidence is error.

Drugs/Drug Attachments: Seagen claims Dr. Lambert focuses on "individual claim elements . . . instead of the claim as a whole."[12] Not so. Dr. Lambert explained, "[t]here cannot be sufficient disclosure of written description for the structure as a whole when, at a minimum, the disclosure for each individual element is deficient."[13] Here, Dr. Lambert appropriately opines that the disclosure for the "drug moiety" and "spacer" limitations are deficient. Seagen seeks to prevent the jury from considering Dr. Lambert's reliable and relevant scientific opinions by misreading *Amgen* to create a "narrow exception" to a (nonexistent) rule that post-filing evidence is inadmissible.[14] To the contrary, *Amgen* reverses a ruling of inadmissibility, holding that "such evidence could have been relevant to determining if the claims were enabled as of the priority date and should not have been excluded simply because it post-dated the claims' priority date."[15] The evidence Dr. Lambert cites, including in Paragraph 110, shows that the POSA would not have been able to make or use the full scope of the claimed invention as of 2004.

Intracellular Cleavage: Seagen seeks to exclude post-filing evidence that demonstrates the incomplete understanding of intracellular cleavage in 2004 and how difficult it is to ascertain the functional intracellular cleavage required by the Drug Moiety Intracellular Cleavage

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Parties dispute the priority date. Seagen does not dispute that if the priority date is determined by the jury to be July 10, 2019, this evidence is appropriate for jury consideration. (*See* Dkt. No. 265, Ex. 1, Opening Report Section VIII.B; *see, e.g.*, ¶ 363.) Nevertheless, even if the priority date is 2004, Dr. Lambert appropriately uses this post-priority evidence to show that these developments were made later in time and could not have been described or enabled earlier.

[12] Dkt. No. 275 at 3.

[13] *See* Dkt. No. 265, Ex. 1, Opening Report Section VII.A.3; ¶ 115. *See also Univ. Rochester v. G. D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2003) (failure to describe limitation regarding compound renders claim to method of using said compound invalid as a matter of law).

[14] Dkt. No. 265 at 8.

[15] *Amgen*, 872 F.3d at 1375.

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Limitation. Unlike *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556 (Fed. Cir. 1983), relied upon by Seagen, Dr. Lambert does not assert that the POSA would have been able to determine intracellular cleavage as of 2004 but that subsequent developments in the art complicated the inquiry. To the contrary, Dr. Lambert concludes that the priority applications do not teach the POSA to make and use an ADC that meets the functional requirements of the Asserted Claims as of 2004, and illustrates that conclusion using art that shows lack of understanding even at much later dates.[16] Enablement is a factual dispute for the jury to decide. Seagen seeks to deprive the jury of relevant facts using inapposite case law as well as faulty scientific presumptions.[17]

D. Dr. Lambert Appropriately Analyzes the Asserted Claims' Functional and Structural Limitations

As Seagen recognizes, the POSA must view the claim as a whole.[18] The Asserted Claims have both structural and functional limitations, and the functional limitations require that the drug moiety of the claimed ADC be intracellularly cleaved ***in a patient***.[19] Dr. Lambert explained that his discussion of therapeutic viability reflects and applies this functional limitation,[20] as the POSA would have to be able to test the ADC to determine if it falls within the Asserted Claims.

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[16] The presumption that ADC internalization is required to cause cell death was incorrect, and Dr. Lambert notes the evolving state of the art has only provided more tools. *See, e.g.*, Dkt. No. 265, Ex. 1, Opening Report ¶¶ 305-10, 314-16 ("[g]iven the understanding in the art in 2003-2004 time period regarding intracellular cleavage, in contrast to the evolution of the art since that time, more disclosure in the specification is required to enable the POSA to determine intracellular cleavage of the ADC's drug moiety in a patient *in vivo*.").
[17] Dkt. No. 265 at 10; *Id.* at 10 n.43; *supra* note 16.
[18] Dkt. No. 275 at Section E.
[19] The language in the Asserted Claims is analogous to the functional claim language in *Idenix* as both required the compound to perform a specified function. *See, e.g.*, *Idenix*, 941 F.3d at 1159.
[20] Dkt. No. 265 at 11-13. Seagen asserts that paragraph 20 is "the only report paragraph Defendants cite in footnote 48," however, Section VII.B (spanning paragraphs 121-332) is also cited, and provides a proper enablement analysis appropriate for jury consideration.

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His analysis does not apply an efficacy (or other unclaimed) requirement. Dr. Lambert's background discussion of design and testing issues such as "off-target toxicities," "reduced cytotoxicity" or "potency," and "limited or mixed FDA success," appropriately provides important context for the challenges faced by the POSA seeking to make and test an ADC with the claimed structural and functional limitations.[21] Further, Seagen's argument that the POSA would know of "a variety of well-known drugs and spacer units,"[22] is specifically the type of factual disagreement the jury should consider and evaluate based on the full record.

E. Consistency of Evidence Should be Considered by the Jury

As explained in Defendants' Opposition, Dr. Lambert does not, as Seagen alleges, ***rely*** on any findings of the EPO or PTAB to ***provide a basis*** for his conclusions. Instead, he merely notes consistency of his own review of the facts with statements made by the EPO and PTAB.[23]

Dr. Lambert similarly does not rely on the opinions of Mr. Manspeizer to form his conclusions, but notes that the analyses of the overlapping underlying facts used by both experts are consistent. Seagen attempts to invoke an inflated standard of admissibility of expert testimony, but determinations of credibility and reliability, as well the weight of the evidence, should be left to the jury.[24]

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[21] For the first time on Reply, Seagen explains its argument regarding "other unclaimed requirements" (Dkt. No. 275 at 4). As Dr. Lambert explains, these are important concepts within the knowledge and consideration of the POSA.

[22] Dkt. No. 275 at 5.

[23] In contrast, in the *Mars* case cited by Seagen, the party attempted to rely on foreign prosecution statements to limit scope during claim construction, and in *Kinetic Concepts*, the party attempted to rely on foreign invalidity findings to affirmatively justify its belief that certain patents were invalid. These cases are thus inapposite here.

[24] *See Mobility Workx, LLC v. Cellco P'ship*, No. 4:17-CV-00872, 2019 WL 5721814, at *6 (E.D. Tex. Nov. 5, 2019) (citing *Wallis v. Hornbeck Offshore Operators*, 2014 WL 3809743, at *1 (E.D. La. Aug. 1, 2014)).

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Respectfully submitted,

/s/ Preston K. Ratliff II

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who have consented to electronic service are being served with a copy of this document via electronic mail on February 3, 2022.

/s/ Preston K. Ratliff II

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